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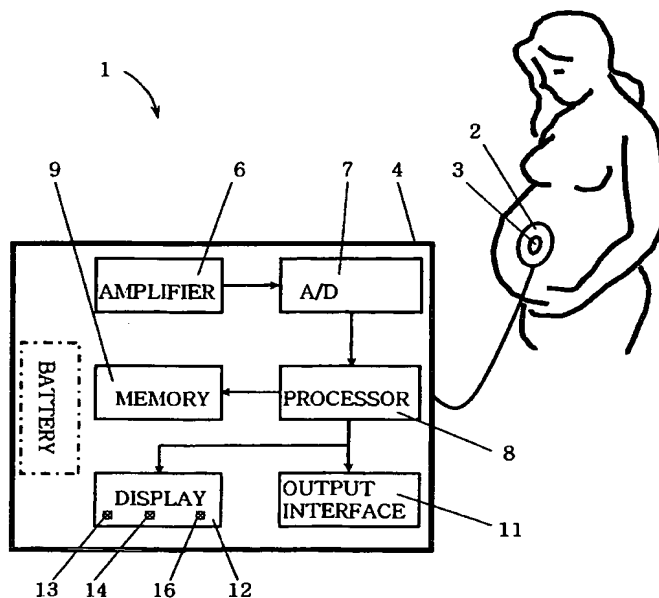
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(54) Title: **BIO-FILTER PAD FOR FACILITATING THE DETECTION OF AN OCCURRENCE OF A PHYSIOLOGICAL ACTION, AND METHOD THEREFOR, AND FETAL ACTIVITY MONITORING APPARATUS**



(57) Abstract: The present invention facilitates the detection of an occurrence of a physiological action imparting a displacement to a body part at a natural frequency signature by virtue of a bio-filter pad including a viscoelastic interior for intimate juxtapositioning against the body part, and having a mechanical resonance frequency midway in the range of the frequency signature associated with the physiological action.

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

BIO-FILTER PAD FOR FACILITATING THE DETECTION OF AN OCCURRENCE OF A PHYSIOLOGICAL ACTION, AND METHOD THEREFOR, AND FETAL ACTIVITY MONITORING APPARATUS

Field of the Invention

5 The invention is in the field of medical diagnostic apparatus and methods for detecting an occurrence of a physiological action in general, and fetal activity in particular.

Background of the Invention

10 Fetal activity has long been recognized as a good predictor of fetal well being as discussed in Fetal Movements In utero – A Review, Sadovsky, E., M.D., Isr. J. Obstet. Gynecol. 1992; 3:27-36. Fetal activity monitoring techniques run the gamut from an expectant mother's subjective assessment of fetal activity via fetal activity monitoring apparatus for monitoring her abdominal movements to *in utero* ultrasound based techniques for "*looking inside*" her uterus. Fetal
15 activity monitoring apparatus is designed to monitor an expectant mother's abdominal movements within the range of 8-25 Hz which is the natural frequency signature of an expectant mother's abdomen. Such abdominal movements are assumed to be largely the result of fetal activity as opposed to uterine contractions, respiratory movements, maternal posture movements, and
20 the like, and therefore the 8-25 Hz natural frequency signature of an expectant mother's abdomen is hereinafter coined as "*natural fetal activity frequency signature*".

 An exemplary fetal activity monitoring apparatus is described in an article entitled "Measurement of Fetal Movements by Moving-Coil Transducer" by
25 Adler D., et al., IEEE Transactions on Biomedical Engineering, Vol. BME-27, No. 12, December 1980 which employs two moving-coil transducers placed on the left and the right sides of an expectant mother's abdomen to pick up abdominal movements. This apparatus requires an about 80 dB electrical signal

amplification for fetal activity detection at least partially being necessitated to overcome the transducers' attenuation of frequencies in the natural fetal activity frequency signature, and offset the apparatus' high sensitivity to electro-magnetic interference (EMI).

5 **Summary of the Invention**

Generally speaking, the present invention is directed toward a bio-filter pad capable of physically amplifying displacements within the range of a natural frequency signature associated with an occurrence of a physiological action for facilitating detection of such an occurrence. This is achieved by the bio-filter pad
10 having a mechanical resonance frequency preferably midway in the range of the natural frequency signature, and a transducer for intimate mechanical coupling therewith also preferably tuned to the same mechanical resonance frequency to increase physical amplification of a displacement, thereby lessening electrical signal amplification requirements by a suitable physiological activity recorder.
15 Transducers employed for implementing the present invention are preferably of the type whose resonant frequency are readily tunable to the desired frequency range, for example, moving coil transducers, however, other types of transducers may also be employed.

At the present time, it is envisaged that the primary application of the
20 present invention will be for fetal activity monitoring purposes in general, and home based fetal activity monitoring purposes in particular but it is also envisaged that the bio-filter pad of the present invention can be adapted for use in sport medicine, rehabilitation, and the like. For fetal monitoring purposes, a bio-filter pad and a transducer preferably each have the same mechanical resonance
25 frequency midway in the range of the natural fetal activity frequency signature whereby they are capable of yielding from about 20 to about 50 physical amplification of an abdominal displacement. By virtue of this physical amplification, a suitably tuned transducer and a fetal activity recorder together constituting fetal activity monitoring apparatus need only a combined about 45

dB electrical signal amplification as opposed to the hitherto required 80 dB electrical signal amplification in the above-mentioned Adler article, thereby also inherently beneficially reducing the latter's EMI sensitivity.

Brief Description of the Drawings

5 In order to understand the invention and to see how it can be carried out in practice, preferred embodiments will now be described, by way of a non-limiting example only, with reference to the accompanying drawings in which similar parts are likewise numbered, and in which:

Fig. 1 is a schematic representation of a first preferred embodiment of a fetal activity monitoring system in accordance with the present invention including a bio-filter pad, a transducer and a fetal activity recorder;

Fig. 2 is a graph showing the natural fetal activity frequency signature of an expectant mother's abdomen;

Fig. 3 is a pictorial representation of the bio-filter pad of Figure 1;

15 Fig. 4 is a cross section view of the bio-filter pad of Figure 1 along line A-A in Figure 3;

Fig. 5 is a graph showing the transmissibility response curve of the bio-filter pad of Figure 1; and

20 Fig. 6 is a schematic representation of a second preferred embodiment of a fetal activity monitoring system in accordance with the present invention.

Detailed Description of Preferred Embodiments

Figure 1 shows a fetal activity monitoring system 1 suitable for home use for providing a visual indication regarding the prevailing level of fetal activity based on detecting an expectant mother's abdominal movements having a typical natural fetal activity frequency signature FS (see Figure 2). The fetal activity monitoring system 1 includes a bio-filter pad 2 adapted for removable intimate adhesion to her abdomen, and having a moving coil transducer 3 centrally disposed thereon for picking up her abdominal movements. The transducer 3 is

connected to a credit-card like, battery powered, fetal activity recorder 4 having an amplifier 6, an A/D converter 7, a signal processor 8, a memory 9, an output interface 11, for example, RS-232, and a fetal activity display 12 for comparing the prevailing fetal activity during a fetal activity monitoring session to a regular level of fetal activity determined on the basis of historical information. The fetal activity display 12 has three LEDs: a green LED 13 for indicating a regular level of fetal activity, an orange LED 14 for indicating a marginally lower than regular level of fetal activity, and a red LED 16 for indicating a significantly lower than regular level of fetal activity. The transducer 3 and the fetal activity recorder 4 have a combined electrical signal amplification in the order of about 45 ± 5 dB.

Figure 3 shows that the bio-filter pad 2 has a topside 17 formed with a resiliently elastic restraining member 18 for intimately mechanically coupling the transducer 3 to the bio-filter pad 2 on its being slid thereunder, and an underside 19 with a peel-off protective liner 21 for exposing an adhesive surface 22 enabling the removable intimate adhesion of the bio-filter pad 2 to an expectant mother's abdomen. The bio-filter pad 2 is preferably circular with a diameter within the range of about 10 cm to about 25 cm, and has a thickness within the range of about 1 mm to about 5 mm. The bio-filter pad 2 has a viscoelastic interior 23 with concentric sections for focusing mechanical energy imparted thereto arising from abdominal movements towards the transducer 3 for enabling detection of most if not all fetal activity and not just limb movements directed towards the transducer 3 (see Figure 4). The viscoelastic interior 23 may be constituted by a solid material, a gel like material, a fluid material, or a combination thereof. The bio-filter pad 2 has a 12 Hz mechanical resonance frequency for physically amplifying displacements within the natural frequency fetal activity signature (see Figure 5), as does the transducer 3. The mechanical resonance frequencies of the bio-filter pad 2 and the transducer 3 can be tested by knocking on them. The mechanical coupling between the bio-filter pad 2 and the transducer 3 are such that they yield from about 20 to about 50

physical amplification of an abdominal displacement, thereby accentuating a natural fetal activity frequency signature.

The fetal activity monitoring system typically replaces an expectant mother's subjective assessment of fetal activity in an otherwise conventional fetal activity monitoring program. Thus, in accordance with her fetal activity monitoring program, she removes a peel-off protective liner from a bio-filter pad, intimately adheres the bio-filter pad onto her abdomen, couples the transducer to the bio-filter pad, and proceeds to record her abdominal movements. In the normal course of events, the green LED will be illuminated and no special action need to be taken. In the event that either the yellow LED or red LED is illuminated during a fetal activity monitoring session, she takes the fetal activity recorder storing all historical fetal activity information to a medical specialist for a professional diagnosis.

Figure 6 shows a fetal activity monitoring system 31 similar to the fetal activity monitoring system 1 except that instead of its fetal activity recorder 32 being a standalone unit, it is intended for removable attachment to a mobile telephone 33 for both being powered thereby, and for connection to a remote server 34 for data processing purposes. To this end, the fetal activity recorder 32 includes a data compression processor 36 for compressing a fetal activity recording for selective transmission to the remote server 34, and an audio output 37 for connection to the mobile telephone's audio input. The results of a fetal activity monitoring session are preferably transmitted by SMS for display on the mobile telephone's display 38.

While the invention has been described with respect to a limited number of embodiments, it will be appreciated that many variations, modifications, and other applications of the invention can be made within the scope of the appended claims. For example, a bio-filter pad may be oval shaped, and may employ different restraining techniques for juxtaposing a transducer against its topside. Also, a recorder, for example, the fetal activity recorders 4 and 36, may be integrally formed with a transducer.

Claims:

1. For use in the detection of an occurrence of a physiological action imparting a displacement to a body part at a natural frequency signature, a bio-
5 filter pad comprising a viscoelastic interior for intimate juxtapositioning against the body part, and having a mechanical resonance frequency midway in the range of the frequency signature associated with the physiological action.
2. The pad according to claim 1 further comprising a peel-off protective
10 liner for exposing an adhesive surface suitable for removable intimate adhesion of the bio-filter pad onto the body part.
3. The pad according to either claim 1 or 2 wherein said viscoelastic interior has concentric sections for focusing mechanical energy imparted to the bio-filter
15 pad due to a displacement of the body part lying thereunder toward a transducer centrally disposed on its topside facing away from the body part.
4. The pad according to any one of claims 1 to 3 and further comprising a
20 restraining member on its topside for removably intimately mechanically coupling a transducer to its topside.
5. The pad according to claim 4 wherein said restraining member slidably receives said transducer.
- 25 6. The pad according to any one of claims 1 to 5 wherein the bio-filter pad is sized and shaped for conforming to an expectant mother's abdomen, and has a mechanical resonance frequency midway in the natural fetal activity frequency signature for fetal activity monitoring purposes.

7. The pad according to any one of claims 1 to 6 wherein the bio-filter pad is intended for single patient single use.

8. A method for detecting an occurrence of a physiological action imparting a displacement to a body part at a natural frequency signature, the method comprising the steps of:

(a) intimately juxtaposing a bio-filter pad against the body part, the bio-filter pad having a viscoelastic interior, and a mechanical resonance frequency midway in the range of the natural frequency signature associated with the physiological action;

(b) intimately mechanically coupling at least one transducer against the topside of the bio-filter pad for generating electrical signals in response to displacements of the body part; and

(c) processing the electrical signals for detecting occurrences of the physiological action.

9. The method according to claim 8 wherein step (a) includes the step of removing a peel-off protective liner from the underside of the bio-filter pad exposing an adhesive surface for removable intimate adhesion of the bio-filter pad onto the body part.

10. The method according to either claim 8 or 9 wherein step (b) includes removably sliding the transducer under a restraining member on the topside of the bio-filter pad.

11. The method according to any one of claims 8 to 10 and further comprising the step of focusing mechanical energy imparted to the bio-filter pad due to a displacement of the body part lying thereunder toward the transducer.

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12. The method according to any one of claims 8 to 11 wherein the bio-filter pad is sized and shaped for conforming to an expectant mother's abdomen, and has a mechanical resonance frequency midway in the natural fetal activity frequency signature for fetal activity monitoring purposes.

5

13. The method according to any one of claims 8 to 12 wherein the bio-filter pad is intended for single patient single use.

14. Fetal activity monitoring apparatus comprising at least one transducer for intimate juxtaposition against an expectant mother's abdomen for generating electrical signals in response to her abdominal movements; and a fetal activity recorder for processing the electrical signals for detecting occurrences of fetal activity,

characterized in that

15 the apparatus has an electrical signal amplification of about 45 ± 5 dB.

15. Apparatus according to claim 14 wherein said fetal activity recorder includes said at least one transducer integrally formed therewith.

20 16. Apparatus according to either claim 14 or 15 wherein said fetal activity recorder has an audio output for interfacing with a mobile telephone.

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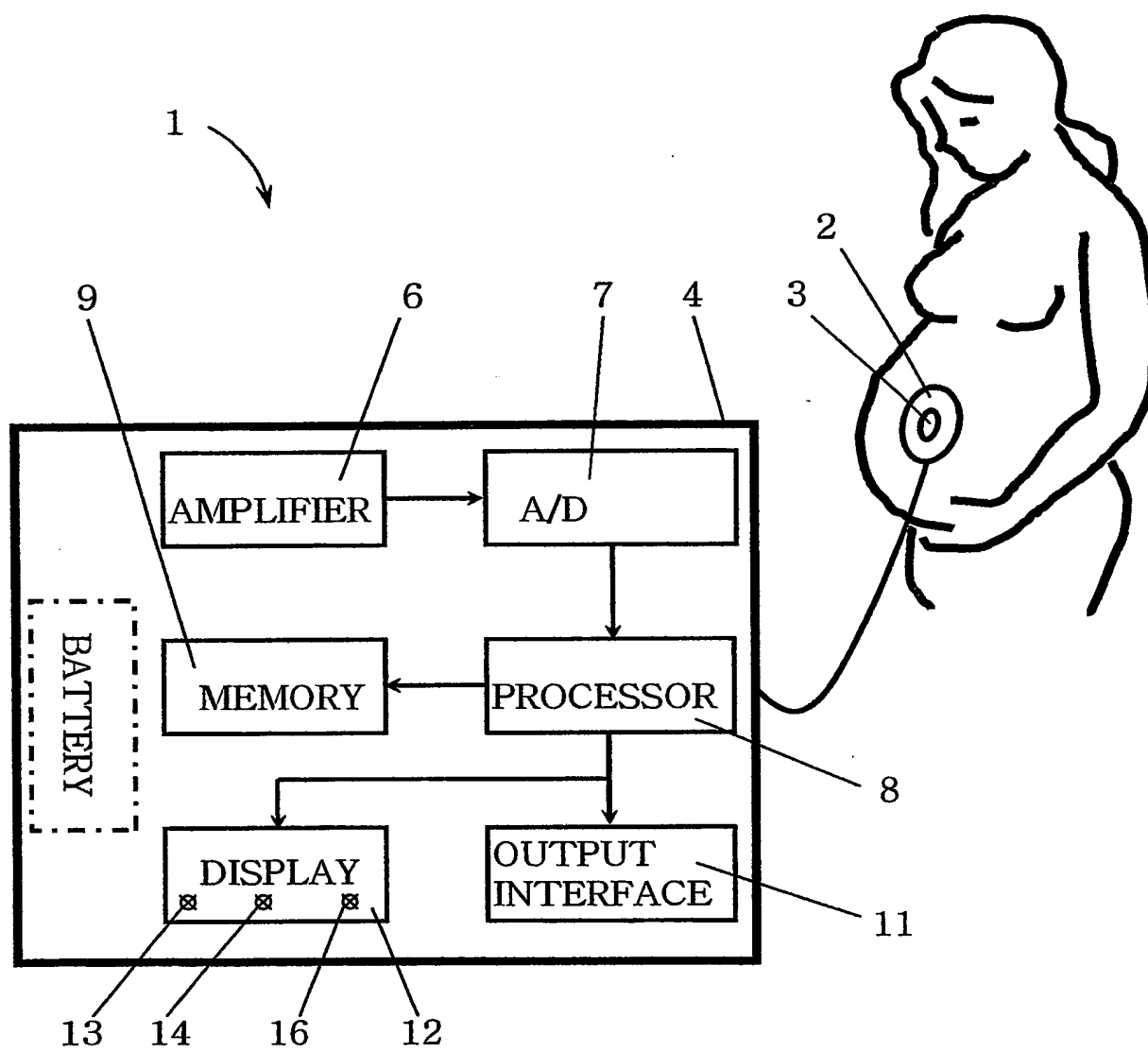


FIG. 1

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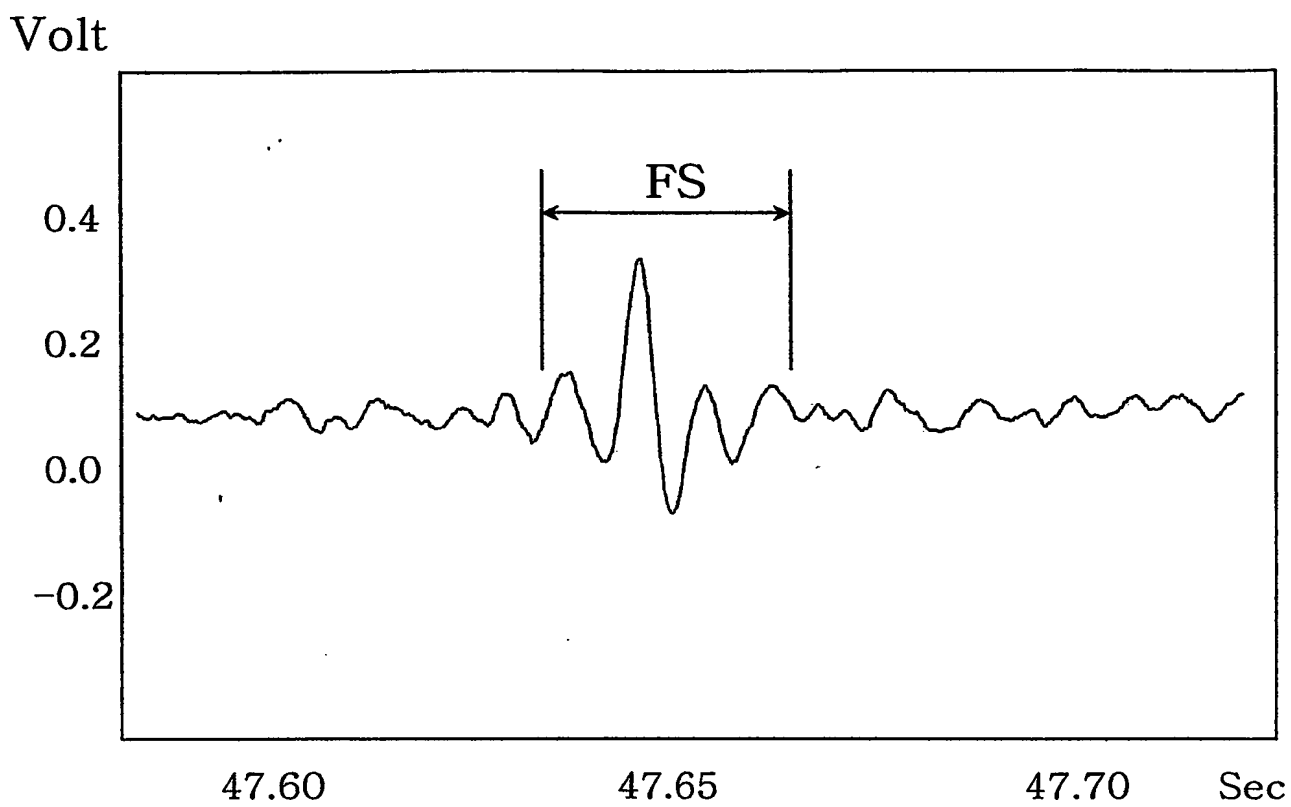


FIG. 2

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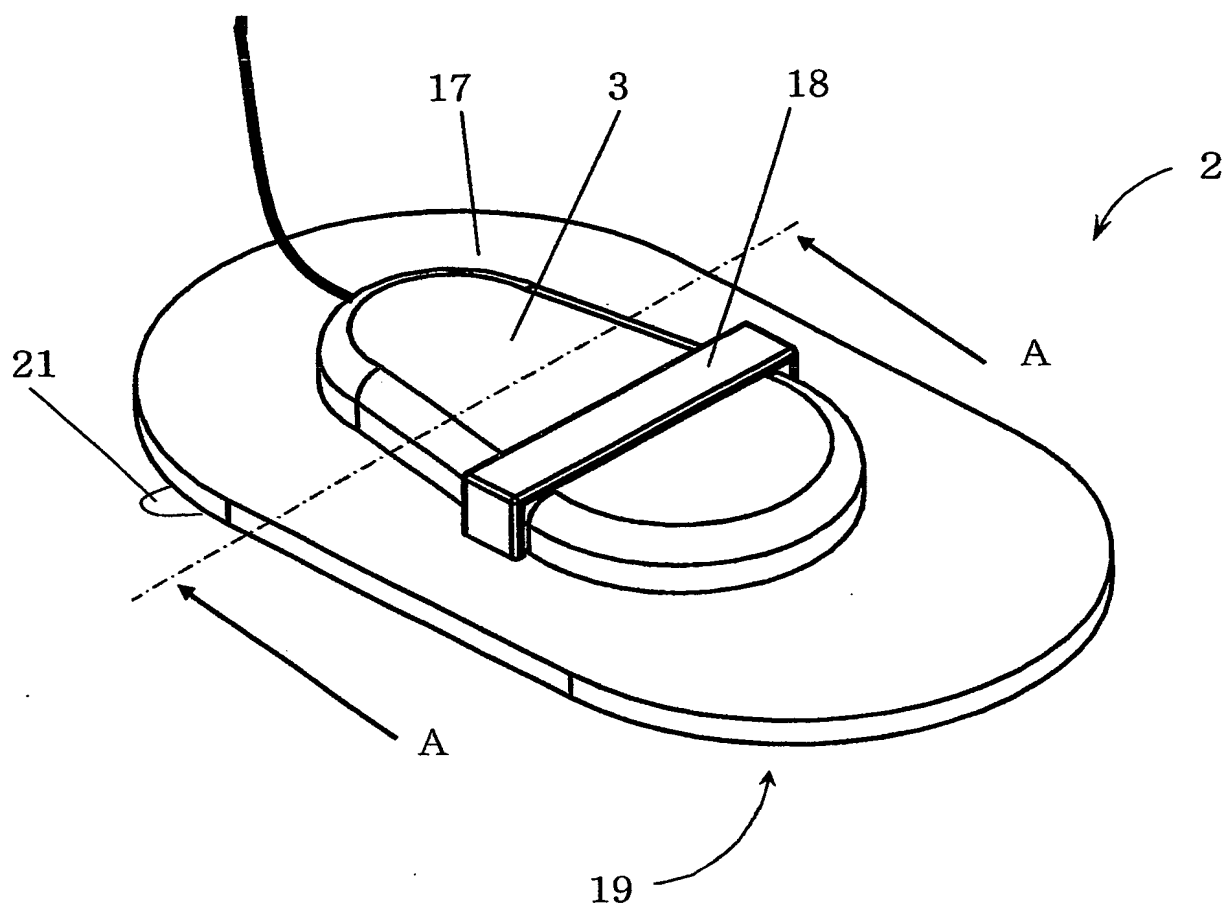


FIG. 3

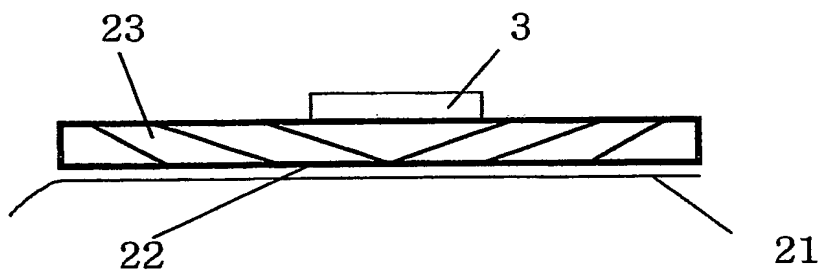


FIG. 4

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AMPLIFICATION

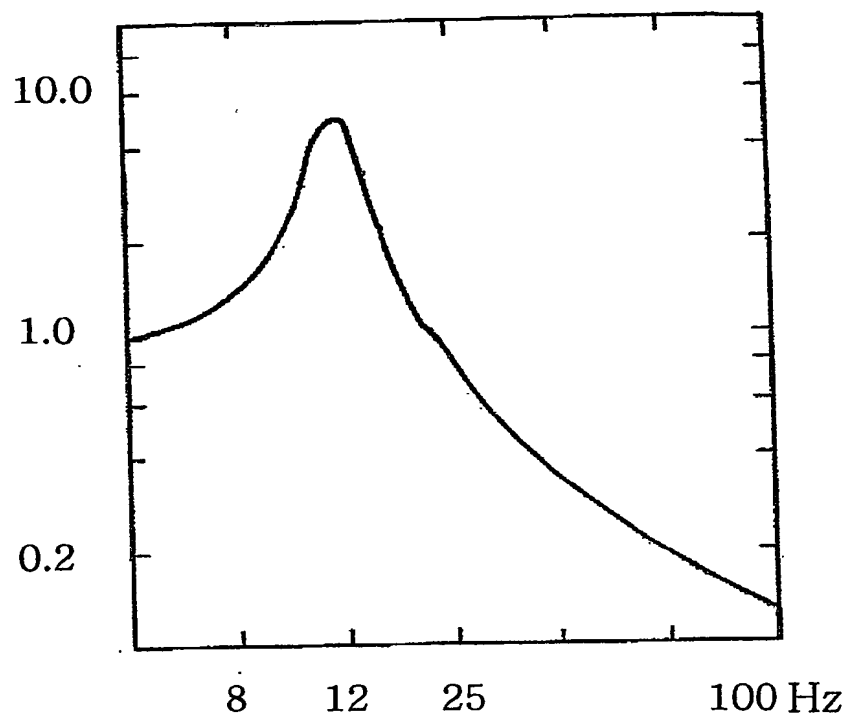


FIG. 5

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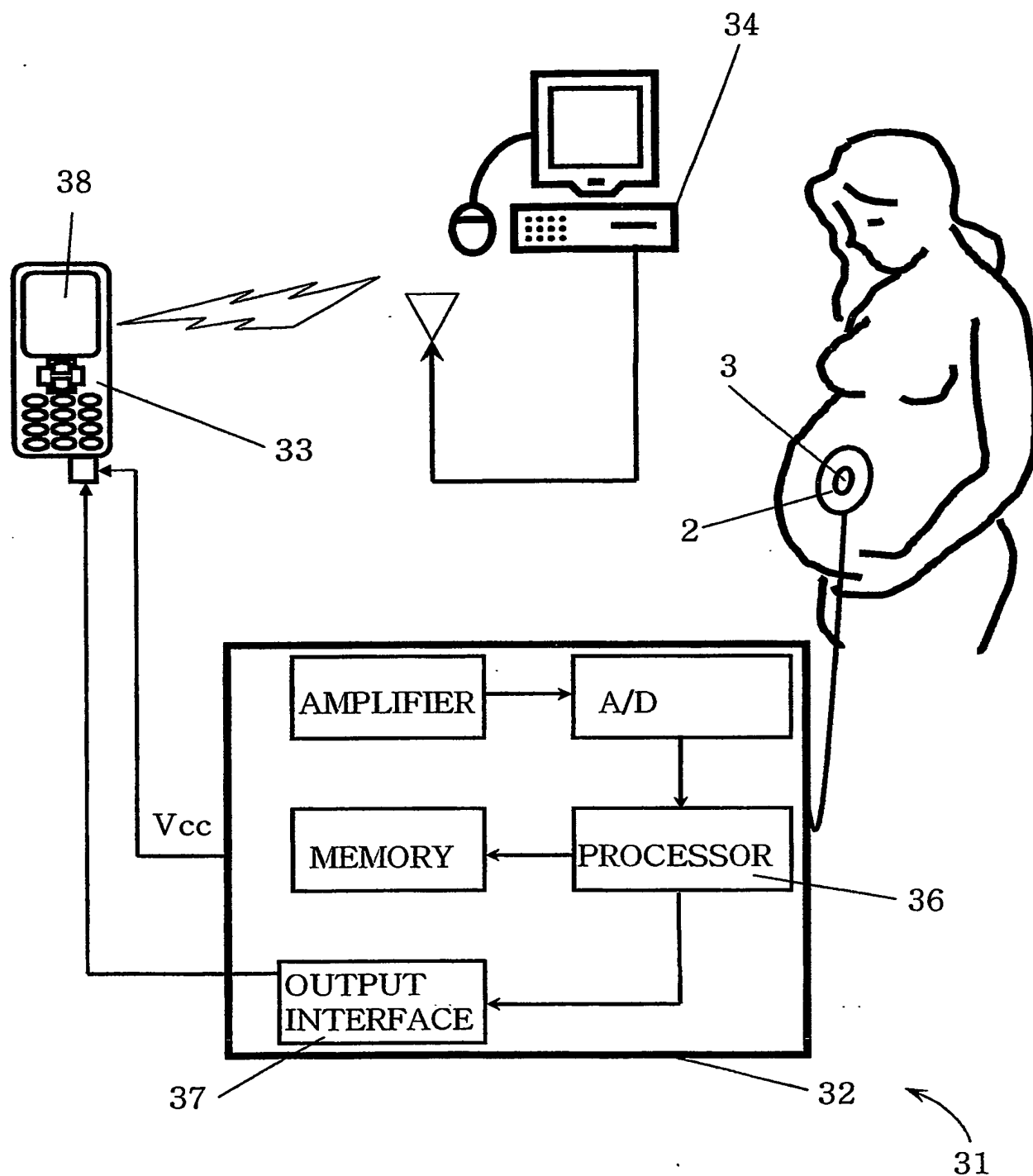


FIG. 6